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A pilot study of pulmonary rehabilitation and chest physiotherapy versus chest physiotherapy alone in bronchiectasis

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Efficacy

Summary

Aim: The aim of our study was to assess the efficacy of pulmonary rehabilitation in addition to regular chest physiotherapy in non cystic fibrosis bronchiectasis.

Methods: Thirty patients with clinically significant bronchiectasis and limited exercise tolerance were randomized into either the control group receiving chest physiotherapy (8 weeks) or into the intervention group, receiving pulmonary rehabilitation in addition to chest physiotherapy (8 weeks).

Both groups were encouraged to maintain their exercise program and or chest physiotherapy, following completion of the study.

Results: End of training (8 weeks)

No improvement in control group.

In the intervention group, incremental shuttle walk test (ISWT) improved by 56.7 m ($p = 0.03$), endurance walk test (EWT) by 193.3 m ($p = 0.01$), Leicester Cough Questionnaire (LCQ) improved by 2.6 units ($p < 0.001$) and St. George's Respiratory Questionnaire (SGRQ) by 8 units ($p < 0.001$).

At 20 weeks (12 weeks post end of training)

No improvement in control group.

In the intervention group, ISWT improved by 80 m ($p = 0.04$) and EWT by 247.5 m ($p = 0.003$). LCQ improved by 4.4 units ($p < 0.001$) and SGRQ by 4 units ($p < 0.001$).

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Conclusion: Pulmonary rehabilitation in addition to regular chest physiotherapy, improves exercise tolerance and health related quality of life in non cystic fibrosis bronchiectasis and the benefit was sustained at 12 weeks post end of pulmonary rehabilitation.

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Introduction

Bronchiectasis is a chronic debilitating respiratory condition due to inflamed and permanently damaged airways. Patients suffer daily cough, excess sputum production and recurrent chest infections. Some patients in addition have wheeze, dyspnoea and reduced exercise tolerance.^{1,2} The cause of dyspnoea and reduced exercise capacity are multifactorial and may include altered pulmonary mechanics, inefficient gas exchange, decreased muscle mass and confounding psychological morbidity.³ This leads to a cycle of reduced exercise capacity, resulting in progressive detraining and further reduced exercise tolerance and health related quality of life (HRQoL).^{3–6}

In 1988, bronchiectasis was described as an “orphan disease” of the airways.⁷ However, more than two decades later, there is little or no evidence for the effectiveness of most of the treatments in bronchiectasis, including inhaled corticosteroids, bronchodilators, hyperosmolar agents, mucolytics and even bronchopulmonary hygiene physical therapy.⁸

Although, regular chest physiotherapy is considered standard in patients with non cystic fibrosis bronchiectasis, there is little scientific evidence to support efficacy and effectiveness.⁹ In 2009, Murray *et al.*, showed by an RCT in non cystic fibrosis bronchiectasis, that regular chest physiotherapy (in patients who did not practice regular chest physiotherapy), led to an improvement in exercise tolerance and HRQoL.¹⁰

Pulmonary rehabilitation is a multidisciplinary approach to treating patients with chronic lung disease and is advocated in the guidelines of management in the American, British and European guidelines.^{11–13} Newall *et al.* showed that pulmonary rehabilitation is effective in improving exercise tolerance in bronchiectasis, but simultaneous inspiratory muscle training was required to maintain the initial improvement.¹⁴

The aim of this pilot study was to compare the effects of regular chest physiotherapy alone in comparison to chest physiotherapy and pulmonary rehabilitation, in patients with non cystic fibrosis bronchiectasis, to determine whether pulmonary rehabilitation has an additional benefit to regular chest physiotherapy.

Methods

Study design

Thirty patients with non cystic fibrosis bronchiectasis, confirmed by high resolution computed tomography (HRCT), were allocated randomly (by a computer generated

random number sequence) to one of the two groups: (1) control group receiving 8 weeks of twice daily chest physiotherapy; and (2) intervention group receiving twice daily chest physiotherapy plus pulmonary rehabilitation. Patients were encouraged to maintain the exercises and or chest physiotherapy, after the intervention ended.

In both groups assessments were performed at baseline, at 8 weeks, and at 12 weeks after completion of study (20 weeks) for each individual patient.

Prior to starting the study, all patients attended the physiotherapy gym and or the laboratory to familiarize themselves with the equipment and to minimize the effects of test habituation. This was done on two separate days to assess reproducibility of tests and this was achieved.

The study was approved by the Lothian Research Ethics committee (Edinburgh, UK) and patients gave informed written consent.

Outcome measures

The primary endpoint was improvement in the incremental shuttle walking test (ISWT).

Power calculation for study

We based the power calculation on a previous study by Newall *et al.*¹⁴ This study was powered to detect a mean (SD) difference of 50 m (using the ISWT) between the groups (assuming an SD of 40 m) would require 11 patients per treatment group with 80% power and a significance level of 0.05. This study was therefore adequately powered for the primary endpoint.

Secondary endpoints were endurance walk test (EWT), health status questionnaires – cough severity using LCQ¹⁵ and health related quality of life using SGRQ,¹⁶ Forced expiratory volume in 1 s (FEV₁), Forced Vital Capacity (FVC), Maximal Inspiratory Pressure (PImax), Maximal Expiratory Pressure (PEmax) and markers of inflammation including, white cell count (WCC), C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR).

Patients

Patients were recruited from South East of Scotland Bronchiectasis Clinic in the Royal Infirmary of Edinburgh, UK, in a prospective study.

Inclusion criteria

(1) All patients had an established radiological diagnosis of bronchiectasis (HRCT of the chest); (2) patients had clinically significant bronchiectasis expectorating mucopurulent

or purulent sputum when clinically stable; (3) clinically stable disease with no requirement of antibiotics in the 4 weeks prior to commencing the study; (4) exercise capacity reduced to disease process; (5) all practicing chest clearance regularly (>4times/week) prior to study entry.

Exclusion criteria

(1) Current smokers or ex-smokers of less than 1 year; (2) >15 pack year history; (3) cystic fibrosis; (4) active allergic bronchopulmonary aspergillosis; (5) active tuberculosis; (6) poorly controlled asthma.

Chest physiotherapy

Chest physiotherapy was carried out using the oscillatory PEP device Acapella Choice® (Smiths Medical ASD Inc., Weston, MA, USA). Patients were individually trained by senior chest physiotherapist (J.L. Pentland). The frequency/resistance dial (range 1–5) was set at three for all participants. This setting was the maximum tolerated by all participants. Patients performed three sets of the following cycle at each session (20–30 min), twice a day. (1). A tight seal was maintained around the mouthpiece. (2). For 10 breaths, patients inhaled to three quarters of the maximum inspiratory capacity then a 3-s breath hold followed by exhalation to functional residual capacity. (3). Then followed by two to three forceful expiratory huffs.

Once the physiotherapist was satisfied with the patients' technique, chest physiotherapy was done at home but was checked at each study visit.

Technique, compliance and occurrence of any adverse effects (specifically, any haemoptysis or increased use of short-acting bronchodilator therapy) were assessed using a diary card, which was reviewed at each visit. Sessions ended with an education session (described below).

Pulmonary rehabilitation

Pulmonary rehabilitation was carried out over 8 weeks in the physiotherapy gym in the Royal Infirmary of Edinburgh. There were 2 supervised sessions per week and 1 unsupervised session at home for 8 weeks. Patients started with a gentle warm up, followed by 10-min sessions each on cardiovascular equipment including the treadmill (Vision™ Fitness, USA), bike (Tunturi®, Netherlands) and ski machine (Welso Skier Plus, Welso™ Fitness Equipment, USA). Patients were exercised at 85% VO₂max (maximal oxygen consumption). All exercises were demonstrated and supervised by trained physiotherapists and modifications of exercises were done, as per patient's ability. Speed/resistance/time/number of rest and final saturations/heart rate and Borg score¹⁷ was recorded, at the end of each intervention.

Sessions ended with a cool down, as in warm up, but slower paced followed by education.

Upper and lower limb exercises

Exercises were started at 60% of patient's 1 repetition maximum (RM), aiming 3 sets of 10. Week 3 progressed to

70% and week 5 to 80%. If patient managed 3 sets of 10 with ease, they were progressed to 1 RM or more, according to patient's ability.

Education session

All patients were educated about coping with breathlessness and the importance of regular chest physiotherapy and given a self-management plan as well as an opportunity to ask relevant questions. Chest clearance techniques were taught. A dietitian discussed healthy eating options and a pharmacist checked inhaler technique.

All patients were encouraged to continue using the acapella, at the end of 8 weeks to aid chest clearance. Once patients completed 8 weeks of pulmonary rehabilitation, they were offered free gymnasium membership for 6 months to encourage patients to continue with the exercise program.

Incremental shuttle walk test (ISWT)

Patients walked a 10 m course mapped out by two cones. The speed gradually increased each minute. The test was stopped if the patient was too breathless or failed to attain the desired speed. The distance walked was recorded in metres.¹⁸

Endurance walk test (EWT)

EWT was performed as described by *Revill et al.*¹⁹ Patients walked along a 10 m course demarcated by 2 cones and turned around cones at either end of the course. The walking pace was controlled by a series of pre-recorded bleeps from the test CD. EWT was performed at 85% of VO₂max, measured from the ISWT.

Health status

Patients were asked to complete both the Leicester Cough Questionnaire (LCQ) and St George's Respiratory Questionnaire (SGRQ) at all review time points. The LCQ has 19 items divided into 3 domains: physical (8 items), psychological (7 items) and social (4 items). The total severity score ranges from 3 to 21, where a lower score indicates a greater impairment of health status due to cough. The MCID for LCQ is 1.3 units.¹⁵ We have validated the Leicester Cough Questionnaire for use in non cystic fibrosis bronchiectasis.²⁰ The SGRQ has 50 items divided into 3 main domains, symptoms, activities and impacts. The total score ranges from 0 to 100, where a higher score indicates a poorer HRQoL. The MCID for SGRQ is 4 units.¹⁶

Lung function

Forced Expired Volume in 1 s (FEV₁), Forced Vital Capacity (FVC) and FEV₁/FVC ratio were recorded, according to national guidelines.²¹

Respiratory muscle strength

Maximum Inspiratory Pressure (MIP) and Maximum Expiratory Pressure (MEP) were measured as per the methods described by Black and Hyatt²² using a handheld mouth pressure meter (MicroRPM Respiratory Pressure Meter, Micromedical Ltd, UK). For measuring MIP, patients were instructed to exhale to residual volume and then inhale forcefully and maintain maximum pressure for 1 s. To measure MEP, patients were instructed to inhale to total lung capacity and then exhale forcefully and maintain maximum pressure for 1 s.

Blood samples

15 ml of venous blood was collected and white cell count, ESR and CRP were measured.

Statistical analysis

All data were analysed using Graphpad prism (Graphpad software, San Diego, CA, USA). Data was normally distributed. For demographic and clinical variables, data are presented as mean (standard error) for continuous variables and *n* (%) for categorical variables unless otherwise stated. Comparison of changes between the 2 groups was

calculated using unpaired *t* tests. A *P*-value of <0.05 was considered statistically significant for each analysis.

Results

Patients

15 patients were randomly allocated in each arm of the study, by a computer generated program (Fig. 1). All 15 patients in the control group completed the study. 3 patients withdrew from the intervention group due to personal reasons (two patients had bereavement in the family; and one patient had a new diagnosis of terminal disease). 2 patients withdrew after week 1 and 1 patient withdrew at week 3. Baseline characteristics of the study population is summarized in Table 1.

1. Exercise capacity (Fig. 2 and Table 2)

End of training

No improvement in acapella group.

In the intervention group, there was an improvement in the ISWT by 56.7 m ($p = 0.03$) and the EWT by 193.3 m ($p = 0.01$).

At 20 weeks

No improvement in acapella group. The mean distance walked at the end of the study was similar to baseline

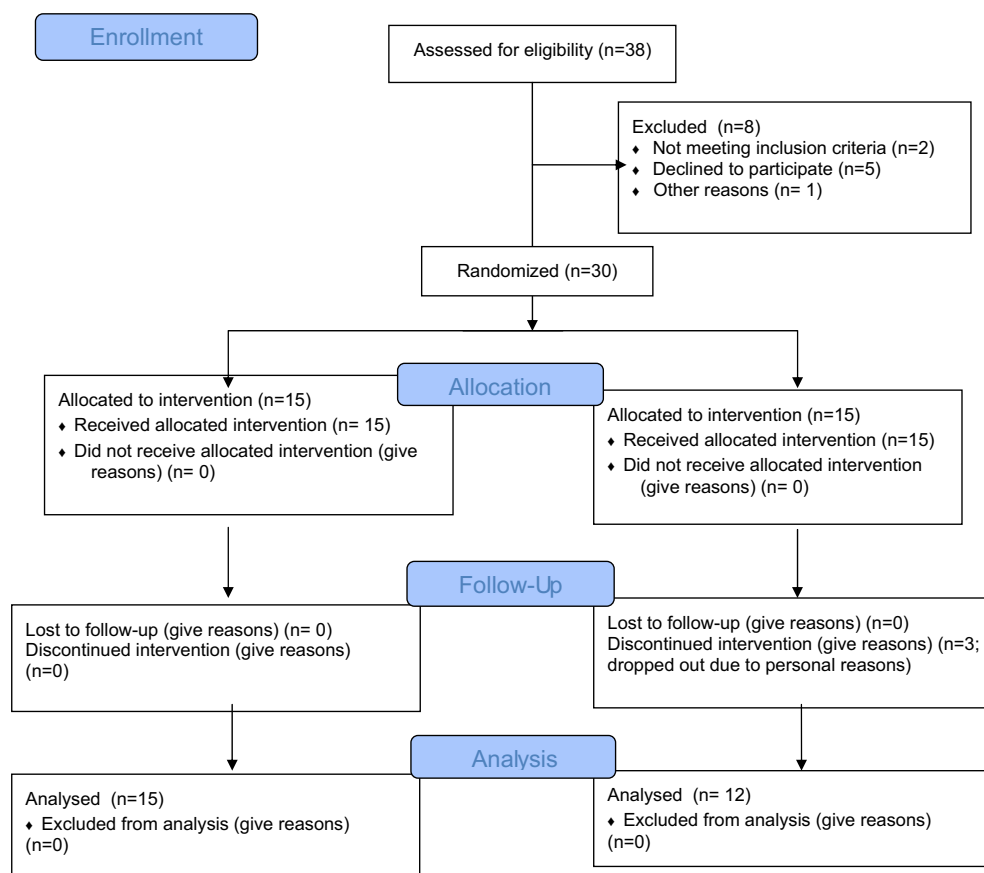


Figure 1 Flow chart from recruitment to completion of study.

Table 1 Baseline characteristics of study population; there was no statistically significant difference between the two groups at baseline.

	Group receiving acapella (n = 15)	Group receiving acapella + pulmonary rehabilitation (n = 12; 3 withdrew)
Age	64.6 (3.4)	64.8 (3.7)
Gender (% male)	40%	66.7%
Smoking status (Never)	33.3%	58.3%
Inhaled corticosteroids	80%	91.6%
Radiological severity (≥3 lobes)	40%	41.7%
Chronically colonized	80%	91.6%
Chronically colonized with <i>Pseudomonas aeruginosa</i>	26.7%	33.3%
FEV ₁ (L)	1.9 (0.3)	1.9 (0.3)
FEV ₁ (% predicted)	72%	76%
Plmax (cm H ₂ O)	56.1 (6.1)	63.4 (9.1)
Plmax (% predicted)	85%	89%
PEmax (cm H ₂ O)	85 (8.2)	73 (10.9)
PEmax (% predicted)	68%	62%
ISWT (m)	343.3 (44.4)	287.5 (50.6)
EWT (m)	1021.4 (144.4)	1102.5 (116.2)

(343.3 m at the start and completion of study). In the intervention group, there was an improvement in the ISWT by 80 m ($p = 0.04$) and the EWT by 247.5 m ($p = 0.003$).

2. Health related quality of life

There was no significant difference in the health status at baseline between the two groups (see Table 3).

End of training

No improvement in acapella group.

In the intervention group, there was a 2.6 unit improvement in the LCQ (the MCID for LCQ is 1.3 units) and

an 8 unit improvement in the SGRQ total score (the MCID for SGRQ is 4 units).

At 20 weeks

No improvement in acapella group.

In the intervention group, there was a 4.4 unit improvement in the LCQ (the MCID for LCQ is 1.3 units) and a 4 unit improvement in the SGRQ total score (the MCID for SGRQ is 4 units) (Table 3).

3. Spirometry and respiratory muscle function

There was no improvement in spirometry or respiratory muscle function in either groups (see Table 4).

4. Inflammatory markers

There was no significant change in the inflammatory makers at the different time points, in either groups and is shown in Table 5.

Discussion

This pilot study in non cystic fibrosis bronchiectasis, found that pulmonary rehabilitation in addition to regular chest physiotherapy led to significant improvement in exercise capacity and health related quality of life as compared to patients practicing regular chest physiotherapy alone, and this was maintained at 12 weeks after the intervention ended. However, this did not result in any significant improvement in the secondary outcome measures-FEV₁, FVC, Plmax, PEmax or inflammatory markers including WCC, CRP and ESR. Based on a previous study by Newall *et al.*,¹⁴ our study was adequately powered to detect a change in exercise capacity.

At our centre, pulmonary rehabilitation included training with 3 different cardiovascular equipments. In addition patients were educated about chest clearance techniques, given self-management plans and inhaler techniques were checked.

Our study showed that pulmonary rehabilitation in addition to regular chest physiotherapy led to improvement

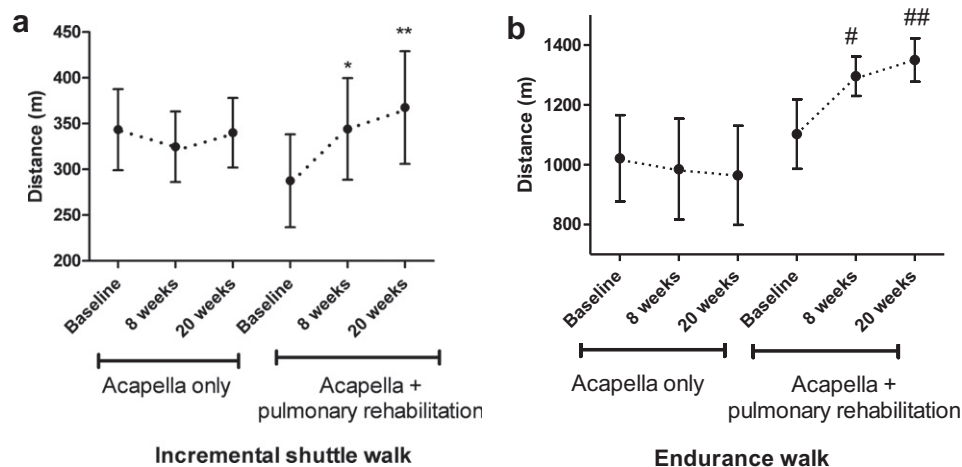


Figure 2 Figure (a and b) showing the mean (\pm SE) of the distance walked in the two groups at time points indicated. P values represent differences between the 2 groups, at time points indicated. * $p = 0.03$; ** $p = 0.04$; # $p = 0.01$, ## $p = 0.003$.

Table 2 *p* values represent difference between groups at time points indicated.

	Group receiving acapella (<i>n</i> = 15)			Group receiving acapella + pulmonary rehabilitation (<i>n</i> = 12)		
	Baseline	8 weeks	20 weeks	Baseline	8 weeks	20 weeks
ISWT (m)	343.3 (44.4)	338.7 (42.2)	343.3 (39.8)	287.5 (50.6)	344.2 (115.5)*	367.5 (61.5)**
EWT (m)	1021.4(144.4)	985 (168.6)	964.3 (165.7)	1102.5 (116.2)	1295.8 (65.8) #	1350 (72.6) ##

p* = 0.03; *p* = 0.04; #*p* = 0.01; ##*p* = 0.003.

Table 3 *p* values represent difference between groups at time points indicated.

	Group receiving acapella (<i>n</i> = 15)			Group receiving acapella + pulmonary rehabilitation (<i>n</i> = 12)		
	Baseline	8weeks	20weeks	Baseline	8weeks	20 weeks
SGRQ	40.6 (3.9)	39.2 (4.5)	45.2 (4.5)	38.6 (6.4)	30.6 (6.6)*	34.6 (7.7)*
LCQ	14.4 (1.5)	14.6 (1.4)	13.62 (1.4)	12.3 (2.3)	14.9 (2.3)*	16.7 (1.8)*

**p* < 0.001.

in both the incremental shuttle walk test and the endurance walk test, in comparison to the group practicing chest physiotherapy alone, on completion of training. This improvement was maintained at 20 weeks (12 weeks post completion of study). Following end of training, patients in both groups were encouraged to maintain their exercise program and or chest physiotherapy.

Pulmonary rehabilitation is now recommended as the standard of care for patients with chronic obstructive lung disease.²³ Exercise and self-management training, as a part of pulmonary rehabilitation program, is a well established and effective intervention in chronic obstructive pulmonary disease. This leads to reduced exacerbations and subsequently health care utilization, improved exercise capacity and health related quality of life.^{24–28} There are marked similarities in the disease manifestations of COPD and bronchiectasis, with both conditions having a primary pulmonary involvement and having secondary peripheral muscle, nutritional and health related quality of life impairment.²⁹ In respiratory medicine there is often extrapolation of treatment modalities for which evidence has been gained in one clinical condition, to another condition. However this needs to be done with caution and needs to be supported by good evidence. In a systematic review in 2002, *Bradley et al.* concluded that there was

a need for well designed, adequately powered, randomized controlled clinical trials to assess the benefit of adhering to different forms of physiotherapy in bronchiectasis.³ Three significant studies addressing chest physiotherapy and pulmonary rehabilitation, in bronchiectasis have been done to date. In 2005, *Newall et al.* showed that in bronchiectasis, pulmonary rehabilitation in addition to inspiratory muscle training (IMT) improved exercise tolerance and health status and this was maintained at 3 months after completion of study.¹⁴ Addition of IMT was required to maintain the longevity of the training effects.¹⁴ In a large retrospective study in 2011, it was shown that pulmonary rehabilitation in bronchiectasis led to significant improvement in patients' exercise tolerance and health status. This was comparable to the improvements in the COPD group receiving pulmonary rehabilitation.³⁰ However, prospective studies are needed to substantiate these findings. In 2009, in a cross over RCT in non cystic bronchiectasis in patients not practicing regular chest physiotherapy, we showed that regular chest physiotherapy in comparison to no chest physiotherapy, led to an improvement in exercise tolerance and HRQoL.¹⁰ There was no improvement in the control group in the current study. This may reflect the fact that all patients, as part of the inclusion criteria, were already practicing regular chest physiotherapy prior to starting the

Table 4 No statistically significant change in secondary outcome measures (FEV₁, FVC, PImax or PEmax) in either the control or intervention group, at any of the time points shown.

	Group receiving acapella (<i>n</i> = 15)			Group receiving acapella + pulmonary rehabilitation (<i>n</i> = 12)		
	Baseline	8 weeks	20 weeks	Baseline	8 weeks	20 weeks
FEV ₁ (L)	1.9 (0.3)	1.9 (0.3)	1.9 (0.3)	1.9 (0.3)	2.1 (0.4)	2.1 (0.4)
FVC(L)	2.7 (0.3)	2.7 (0.3)	2.8 (0.3)	2.9 (0.3)	3.1 (0.4)	2.9 (0.4)
PImax (cm H ₂ O)	56.1 (6.1)	62 (4.8)	51.1 (4.4)	63.4 (9.1)	70 (12.9)	75.1 (11.9)
PEmax (cm H ₂ O)	85 (8.2)	90.3 (9.1)	77.6 (10.7)	73 (10.9)	87.7 (12.8)	93.8 (15.2)

Table 5 No statistically significant change in secondary outcome measures (WCC, CRP or ESR) in either the control or intervention group, at any of the time points shown.

	Group receiving acapella (n = 15)			Group receiving acapella + pulmonary rehabilitation (n = 12)		
	Baseline	8weeks	20weeks	Baseline	8weeks	20 weeks
WCC*10 ⁹ /L	6.5 (0.6)	6.9 (0.8)	6.9 (0.8)	8.3 (0.9)	8.2 (0.8)	8.1 (0.8)
CRP mg/L	4.9 (1.2)	5.5 (1.6)	5.2 (1.3)	7.9 (2.9)	9.5 (2.6)	5.2 (1.6)
ESR mm/hr	14.9 (2.3)	12.1 (2.2)	13.7 (3.3)	14.2 (2.7)	18.2 (4.3)	15.3 (2.9)

study. Larger studies are needed with physiotherapy alone to evaluate other outcome measures such as exacerbations.

Limitations

We acknowledge that our study had limitations. Firstly, the size of the study was small. Secondly no information was collected on the intensity of ongoing training activities in the intervention group between weeks 8 and 20. Although all patients in this group were offered free gymnasium membership for 6 months, it would have been helpful to know the take up and frequency of exercise intervention. Finally exacerbations were treated by their primary care physician and this data was not collected for this pilot study.

Conclusion

In summary, our pilot study showed that pulmonary rehabilitation improved exercise capacity and health related quality of life and this was sustained at 12 weeks post completion of intervention. Large multicentre studies are needed to address key secondary endpoints such as the effect on exacerbations.

Ethical approval

IRB Statement: IRB Name: South East of Scotland Research Ethics Committee 2; Approval number: 08/S1102/40.

Conflict of interest statement

None declared.

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